REMARKS/ARGUMENTS

Applicant notes the Examiners allowance of Claims 47-66, and that they are allowable over the prior art of record. However, the Examiner has withdrawn allowance of Claims 1-11 because of newly discovered reference to Page et al U. S. Patent No. 5,215,522.

Applicant has set forth amended independent Claims 1 and 8 with clear and distinct language to more clearly distinguish over the prior art of Page et al '522.

To begin with, the Examiner has rejected Claim 1 on the statement that Page et al '522 teaches a suction control valve used in a suction system "wherein the system is a closed tracheal suction system." This statement is incorrect. The Page et al suction control valve is specifically designed and will only function in "an open type of respiratory system" (Page et al Column 1, Lines 35-37) and provides a "single use disposable non-ventilating aspirating device" (Column 1, Lines 55-58). Page et al in '522 specifically states that there are two categories of medical aspirating devices which are first closed systems left connected for long periods of time to a ventilator system and used multiple times repeatedly and the second is open style systems which use a single use disposable device not remaining connected to a ventilator (Column 1, Lines 28-

37). See attached Fig. 1 of Page which clearly shows a single use system with no ventilator attachment provided.

The present invention suction control valve is specifically designed to be used primarily in a closed system although it can be used in both closed and open while the Page et al '522 suction control valve will only function in open systems because it is not designed to be used in conjunction with a ventilator circuit nor will it prevent the loss of ventilation out the suction control valve (see Page 2 of pending application).

In addition, the Examiner goes on to reject Claim 1 on the basis that the "piston portion of Page's suction control valve hermetically seals off fluid and air flow communication between the suction tube and the source of suction." This statement is also incorrect. Hermetic is defined as providing an airtight seal. Page et al '522 specifically **teaches away** from an airtight internal hermetic seal which is the opposite of one of the primary novel teachings of the suction control valve of the present invention. The suction control valve described in Figures 8 and 9 of Page et al '522 relied upon by the Examiner simply has a flat valve plate 286 loosely fitted into valve body slot 208. The "width and thickness of the valve plate 286 are slightly less than the width and thickness of valve slot 208" (Column 10, Lines 47-64). This means that there is a pre-determined space or gap

between valve plate 286 and valve slot 208 (Column 10, lines 60-63). Further, the valve plate is specifically designed to provide a **release of air** between the valve plate 286 and valve slot 208 during actuation of the valve (Column 11, Lines 47-49).

This gap providing a release of air (non-hermetic seal) is apparently in the present applicant's opinion critically necessary to the operation of the valve since any teaching of a structural seal between the valve plate 286 and the valve slot 208 could result in a malfunction of the valve caused by buckling or distortion of the rubber molded valve plate 286 when the actuator 282 is depressed to apply suction.

Thus there is no leak proof airtight hermetic seal within the Page et al '522 valve illustrated and described in FIGs 8 and 9 as is the case with the suction control valve of the present invention.(see Page 9 of present invention).

In addition, "the actuator 282 may reciprocate up and down loosely through aperture 316" (Column 11, Lines 12-16) in Page et al '522. The suction control valve of Page et al '522 illustrated and described in Figures 8 and 9 could not prevent the loss of positive pressure ventilation out the suction control valve

nor act to seal off any leakage of suction when the valve is left attached to a suction line.

By comparison, the suction control valve of the present invention as described on Pages 9 and 10 has a closed piston portion which includes "A leak proof and airtight slideable seal." As such, Claim 1 now has amended language which clearly states that the suction system has a plunger which includes a piston portion and most importantly that the piston portion includes a leak proof and airtight slideable seal in its non-suction applied position. This language clearly distinguishes over the non-airtight Page et al '522 valve and all the other known prior art suction control valves used in closed suction systems. Likewise, Claim 8 now has identical amended language used in Claim 1 and dependent Claims 2, 4, 5, 6, 7, 9, 10, 11 rely upon now amended independent Claims 1 and 8. As such, it is believed that independent amended Claims 1 and 8 and their dependent Claims 2, 4, 5, 6, 9, 10 and 11 are in a position for allowance.

For the record, the applicant wishes to thank the Examiner for bringing Page et al '522 patent to his attention for it has sparked some considerable research as to the allowance of the claims contained in the Page et al '522 patent.

Note that the present applicant (Russo) has cited and described the limitations of prior art closed system suction control valves to Palmer U.S. Patent No. 4,569,344 and to Hollister U.S. Patent No. 5,073,164 in his pending application. As mentioned in a previous Office Action response on the pending application, the U.S. Court of Appeals for the District of Utah in Case No. 00-1393 clearly defined the Palmer '344 suction control valve to be limited to a static seal rather than the dynamic seal of the type disclosed as the suction control valve of the present invention.

Unexplainably, the Page et al '522 patent has over 100 prior art references and multiple cited publications, but does not cite the most relevant Hollister patent '164 which issued a full 1-½ years before issuance of the Page et al '522 patent. The Hollister '164 patent goes on to state that the Hollister suction control valve is commercially available and in wide use under the trade designation Steri-Cath® Model No. 6100 from Smiths Industries Medical Systems (Column 1, Lines 48-53). This means that the Hollister '164 suction control valve was in commercial distribution prior to the May 2, 1990 filing date of the Hollister patent which is a full year prior to the April 5, 1991 filing date of the Page et al '522 patent.

Further, the Page et al '522 patent is assigned to Ballard Medical Products which is a direct competitor to Smiths Industries Medical Systems. Further, evidence of the commercial availability and public use of the Smiths Steri-Cath® suction control valve are contained in the attached FDA Notice of marketing approval dated July 12, 1990 (yellow highlighted) along with Steri-Cath® literature from that time which clearly shows the Hollister '164 catalog number suction control valve. Even more disturbing is the fact that Hollister '164 illustrates and describes a suction control valve whose function, structure and operation is described in the allowed claims of the much later issued Page et al '522 patent (see Hollister '164 FIG. 3, Column 4, Lines 53-65). Clearly, Hollister '164 should have been a major part of the review of the Page et al '522 patent application. Of course, as described on Pages 2 and 3 of the pending application, the Hollister '164 Steri-Cath® suction control valve has an obstructed flow path in the suction applied position and has no teaching of an air and fluid tight slideable seal.

As such, favorable consideration and allowance of Claims 1-11 is warranted and requested at this time. However, if the Examiner sees language chances that he believes better defines over the prior art relied upon, such input in the furtherance of allowance in support of the application is welcome.

Appl. No. 10/058,540
Amdt. dated March 10, 2004
Reply to Office Action of January 23, 2004

Respectfully submitted,

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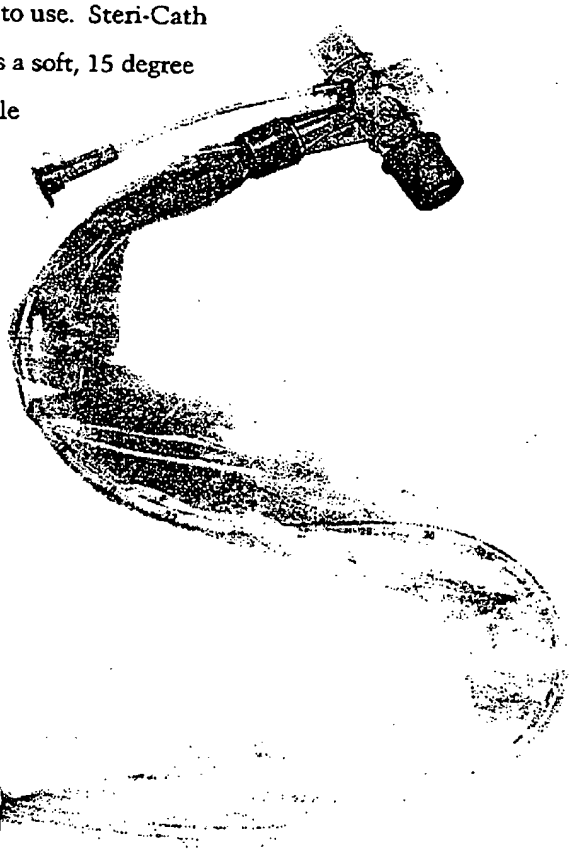
Tel. 401/431-1320

Attachments (5 pages)

Attachment
Ser. No.
10/058540

Steri-Cath Closed Ventilation Suction Systems

All Concord® Steri-Cath® Suction Systems are designed for tracheal suctioning of critically ill patients on ventilatory support systems. The Steri-Cath Systems reduce the risk of contamination by eliminating clinician contact with the catheter. The systems help to reduce oxygen desaturation by allowing clinicians to constantly ventilate patients. These systems are cost effective and convenient to use. Steri-Cath Systems feature the calibrated Maxi-Flo® catheter. The distal tip has a soft, 15 degree beveled tip with smooth lateral eyes. The thumb valve allows simple "on-off" manipulation of the suction source and its raised edges prevent the valve from being inadvertently activated. A light-weight, clear T-piece connects the patient's endotracheal or tracheostomy tube with the ventilator breathing circuit, allowing simultaneous ventilation and suctioning. Steri-Cath is available with a single lumen or dual lumen catheter. Each kit contains a swivel, Trac-Wedge® and patient label with day of the week stickers.



The safe system that gives you more.

Eliminates Aerosolization

- Closed ventilation suction system reduces cross-contamination

Easy to Use

- Remains connected to the patient, eliminates set-up time

Reduces O_2 Desaturation

- Provides for continuous ventilation

Lightweight, Fixed T-Piece Design Reduces Dead Space

- Less weight reduces torque on endo/trach connection

Attachment
Ser. No. 10/058540

ORDERING INFORMATION

STERI-CATH CLOSED VENTILATION SUCTION SYSTEMS

Cat. No.	French Sizes	Description	Units Per Case
6100	10, 12, 14, 16	Steri-Cath single lumen	20
6101	12, 14	Steri-Cath single lumen, tracheostomy size	20
6102		15mm/22mm adaptor	50
6103		15mm/22mm adaptor with 6" flex tube	50
6104	14, 16	Steri-Cath single lumen w/one-way valve	20
6105		Oral Cath, oral care system	20
6106	14, 16	Steri-Cath single lumen lavage 15ml saline vials	20
6107		15mm/22mm adaptor with 3" flex tube	50
6108	14	Steri-Cath single lumen, coudé	20
6109	14	Steri-Cath single lumen, tracheostomy size w/one-way valve	20
6110	12, 14, 16	Steri-Cath dual lumen	20
6111	12,14fr	Steri-Cath dual lumen, tracheostomy size	20
6116	14, 16	Steri-Cath dual lumen lavage 20ml saline vials	20
6117	14, 16	Steri-Cath dual lumen lavage 15ml saline vials	20
6118	12, 14, 16	Steri-Cath single lumen 15mm/22mm with 3" flex tube	20
6119	14	Steri-Cath single lumen tracheostomy size 15mm/22mm with 3" flex tube	20
6127		15ml Modudose® saline vials	144
6128		20ml Dey Vial® saline vials	100
6146	14	Steri-Cath single lumen lavage tracheostomy size, 15ml saline vials	20
6166	14	Steri-Cath dual lumen lavage tracheostomy size 20ml saline vials	20
6186	14, 16	Steri-Cath single lumen lavage 15ml saline vials w/one-way valve	20

All Steri-Cath Suction Systems contain a swivel, Trac-Wedge and patient label.

Attachment Ser. No. 10/058540

smiths

Product code s

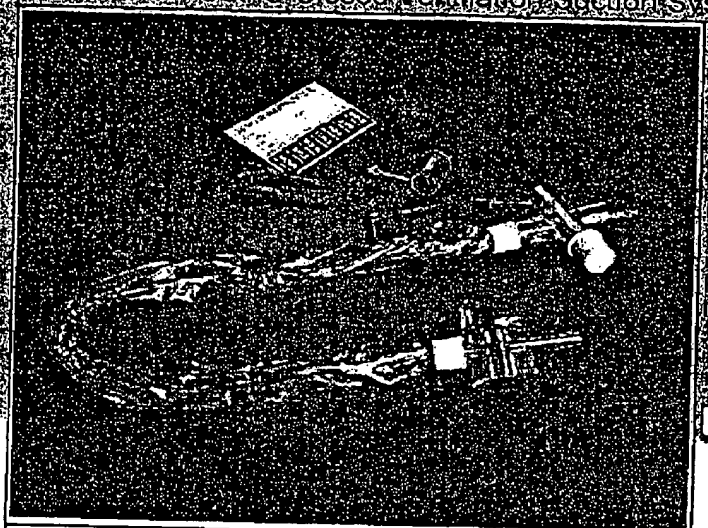
Respiratory Care

- Home
- Profile
- Careers
- Literature
- Latex list
- Contact/ ordering

Samples @ PORTEX.com

Respiration Care | Suction Catheters and Accessories | Steri-Cath® Closed Ventilation Suction Systems

Portex Steri-Cath® Closed Ventilation Suction Systems



Steri-Cath® systems are s
with single lumen or dual
catheter. Systems contain
MDI adapter.

Trac-Wedge™ device and
tube with day or 8 week s
Economy kits include a ma
tube but swivel elbow kit
include the MDI adapter. All
Portex® Steri-Cath® System
latex-free.

Request sample

Steri-Cath® suction systems are designed for airway suctioning of critically ill patients ventilatory support.

Steri-Cath® systems reduce the risk of contamination by isolating clinician contact with the cat The systems help reduce oxygen desaturation by allowing constant patient ventilation. These systems are cost effective and easy to use.

Steri-Cath® Systems Feature the Calibrated Maxi-Flo® Catheter

- The distal tip has a soft, 15° bevel with smooth lateral eyes
- The thumb valve allows simple "on-off" manipulation of the suction source, and its raised ec reduces the risk of the valve being inadvertently activated
- A lightweight, clear T-piece connects the patient's endotracheal or tracheostomy tube with t breathing circuit, allowing suctioning during mechanical ventilation without circuit disconnectio

Steri-Cath® Single Lumen Systems

Reference code	Kit Components	French Sizes	Units Per Case
6100-xx	Single Lumen Steri-Cath® System Swivel MDI Adapter Trac-Wedge™ Device	10, 12, 14, 16	20

Attachment
Ser. No. 10/058 540

510(k) Premarket Notification Database

Device Classification Name	Catheters, Suction, Tracheobronchial
510(K) Number	K902383
Regulation Number	868.6810
Device Name	Steri-Cath(Tm)
Applicant	Concord/Portex 15 Kitt St. Keene, NH 03431
Contact	Robert Wheeler
Product Code	BSY
Date Received	05/30/1990
Decision Date	07/12/1990
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Anesthesiology
Review Advisory Committee	Anesthesiology
Statement/Summary/Purged Status	Purged, No Summary Or Statement
Type	Traditional
Reviewed By Third Party	No

Database Updated 2/06/2004

US005215522A

United States Patent [19]

Page et al.

[11] Patent Number: 5,215,522

[45] Date of Patent: Jun. 1, 1993

Attachment Ser. No. 10/058 540

[54] SINGLE USE MEDICAL ASPIRATING DEVICE AND METHOD

[75] Inventors: Larry E. Page; Darrel Palmer, both of Sandy, Utah

[73] Assignee: Ballard Medical Products, Draper, Utah

[21] Appl. No.: 682,165

[22] Filed: Apr. 5, 1991

Related U.S. Application Data

[60] Continuation of Ser. No. 28,805, Mar. 23, 1987, abandoned, which is a continuation-in-part of Ser. No. 917,866, Oct. 14, 1986, abandoned, and a continuation-in-part of Ser. No. 916,341, Oct. 7, 1986, Pat. No. 4,696,296, which is a division of Ser. No. 767,400, Aug. 20, 1985, Pat. No. 4,638,539, which is a division of Ser. No. 633,570, Jul. 23, 1984, Pat. No. 4,569,344.

[51] Int. Cl.[5] A61M 1/00

[52] U.S. Cl. 604/33; 604/35; 604/118; 604/163; 604/167; 604/241; 128/207.16; 251/318; 251/331; 251/335.2; 251/336; 137/903

[58] Field of Search 128/207.16, 200.26, 128/207.14, 207.15; 604/33, 35; 118, 119, 159, 163, 167, 171, 249, 27, 28, 30, 32, 34, 246, 248, 250; 251/331, 335.2, 318, 336, 346-368; 137/903

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(List continued on next page.)

Primary Examiner—Randall L. Green
Assistant Examiner—K. M. Reichle
Attorney, Agent, or Firm—Lynn G. Foster

[57] ABSTRACT

A reliable, contamination-resistant, single-use, disposable, medical, non-ventilating, aspirating device and method. The device releasibly connects to and aligns with an indwelling endotracheal tube to accommodate advancing of an aspirating catheter tube of the device by manual manipulation through a sterile, flexible envelope and selective evacuation of lung secretions through a closed and sterile two-position, normally-closed, manually-operable valve at the proximal end of the device, while simultaneously accommodating voluntarily respiration by the patient.

10 Claims, 6 Drawing Sheets